EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-OP-45090 *The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 17-OP-45004	MDL No. 2804 Case No. 17-md-2804

EXPERT REPORT OF DR. ANUPAM B. JENA, MD, PhD

May 10, 2019

59. Although Dr. McCann does not choose a preferred methodology, Mr. Rafalski suggests that this method "provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size."[91] But Mr. Rafalski does not explain why Rite Aid Mid-Atlantic's suspicious order monitoring did not meet the relevant regulatory requirements. Furthermore, Mr. Rafalski's opinion that the first method is "an initial trigger" and a "first step" imply that this method is not sufficient on its own.

2. "Twice Trailing Twelve-Month Average Pharmacy Dosage Units"

60. Under Dr. McCann's second approach, transactions are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy in a calendar month to be more than two times the average dosage units shipped to all retail and chain pharmacies served by the distributor in the last 12 months.[92] This approach applies a single monthly threshold across all pharmacies to which Rite Aid Mid-Atlantic distributed.

61. Applying a national average to establish a common threshold for all pharmacies does not make economic sense as a means of identifying suspicious prescription opioid distributions for the obvious reason that pharmacies vary in the size and composition of the populations they serve. A pharmacy serving a large population would be expected to distribute larger quantities of opioids than a pharmacy serving a smaller population during a fixed period of time, all else equal. Similarly, a pharmacy located next to a major hospital or set of large dental clinics would be expected to dispense more opioids than otherwise similar pharmacies. Consistent with this logic, Joseph Rannazzisi, former Deputy Assistant Administrator for the Office of Diversion Control at the DEA, testified that whether an order is identified as suspicious depends on where the customer is situated, for example whether the customer is close to a

---

[91] Rafalski Report, p. 46 ("…it is my opinion to a reasonable degree of professional certainty that applying the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (2017) provides a reasonable estimate and an initial trigger and first step to identifying orders of unusual size. [Footnote: This approach does not take into consideration unusual pattern or frequency.] *See* Methodology A above. Pursuant to *Masters*, 'as a matter of common sense and ordinary language, orders that deviate from a six-month trend are an "unusual" and not "normal" occurrence' *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 216 (D.C. Cir. 2017). I say this understanding that this litigation will be advanced by selecting a methodology quantifying a volume of pills that entered CT1 jurisdictions unlawfully and providing this data to an economist to measure the harm caused by this volume.").

[92] McCann Report, ¶ 136.

hospital or in a rural area.[93] This makes sense because using a national average to establish a common threshold across all pharmacies will mechanically cause shipments to the pharmacies with the largest volumes of business to be flagged as suspicious, even when the shipments are in line with the pharmacy's historical volume of prescriptions and the medical needs of the local community. This method is therefore not a reliable method for identifying shipments at risk of diversion. Furthermore, using an average that is not pharmacy-specific has been criticized by Plaintiffs' own expert, Matthew Perri.[94]

62. While Dr. McCann appears to have intended to use the national average of Rite Aid Mid-Atlantic's distribution,[95] in practice he used the average for Rite Aid pharmacies in Cuyahoga and Summit Counties rather than the national average.[96] Applying the national average for Rite Aid Mid-Atlantic reduces the percentage of flagged transactions into both Cuyahoga and Summit Counties.[97]

3. "Three Times Trailing Twelve-Month Average Pharmacy Dosage Units"

63. Dr. McCann's third approach is the same as the second approach, but the threshold is raised from twice to three times the average shipment of the past 12 months.[98] As such, all criticisms described in the previous section also apply to this method. As described above, for Rite Aid Mid-Atlantic, Dr. McCann used the average for Rite Aid pharmacies in Cuyahoga and Summit Counties rather than the national average. Applying a national average for Rite Aid Mid-

---

93 Rannazzisi Deposition, pp. 274-275 ("Q. It's a business decision as to whether something is a suspicious order as well, correct? A. Yes. Q. And it may be that one business faced with a particular order makes a different decision on the exact same order than another business, correct? […] A. It depends on the type of due diligence they're doing on their customers; whether they know their customers and what their customers' normal ordering patterns are; where is their customer situated; is the customer close to a hospital; is the customer close to -- is in a rural area. There's so many dynamics that the drug enforcement administration doesn't have. Only the business, the distributor, the registrant has that information.")

94 "In my opinion, the Pro Compliance report does not correctly assess the appropriateness of dispensing of controlled substances at Cherokee Pharmacy for the following reasons: The Pro Compliance report provides statistics on drug utilization that incorrectly compares the data from Cherokee Pharmacy to national averages, not similar pharmacy businesses." Expert Report of Matthew Perri III, *In the United States District Court for the District of South Carolina Spartanburg Division, JM Smith Corporation v. Cherokee Pharmacy and Medical Supply, Inc., et al.,* August 6, 2014, ¶ 31.

95 Second Supplemental Expert Report of Craig J. McCann, April 15, 2019, footnote 13 ("In the McCann Report, I reported the result of comparing transactions with Dispensers to two times, and three times, transactions with similar pharmacies nationally.").

96 McCann Report backup, Step0_Find_12M_USA_Avg.m; and CHM_AveX3_DU.xlsx.

97 *See* backup materials.

98 McCann Report, ¶ 140.

Atlantic reduces the percentage of flagged transactions into both Cuyahoga and Summit Counties. For example, applying a national average reduces the percent of flagged Rite Aid Mid-Atlantic transactions into the Cuyahoga County by almost 50 percent (from 12.2 percent to 6.5 percent).[99] Since the thresholds in this methodology are higher than those in method 2, the percent of flagged Rite Aid Mid-Atlantic transactions are lower.

4. "Maximum 8,000 Dosage Units Monthly"

64. Under Dr. McCann's fourth approach, transactions are flagged if they cause the number of dosage units shipped by the distributor to that pharmacy to exceed 8,000 dosage units in a calendar month.[100] In other words, it is presumptively suspicious for any pharmacy, *regardless of its size*, to receive shipments of more than 8,000 dosage units in a calendar month.

65. As with Dr. McCann's second and third approaches, this approach applies a common monthly threshold across pharmacies, ignoring any variation in the size and composition of the populations the pharmacies serve.

66. Dr. McCann provides no source for the 8,000 dosage unit threshold, but I understand this methodology appears in a McKesson document that outlines this as a McKesson-specific threshold as part of its "Lifestyle Drug Monitoring Program."[101] As described to the DEA, McKesson's "Lifestyle Drug Monitoring Program" excluded national chain pharmacy accounts, including Rite Aid, because the DEA had not identified any issues with those accounts.[102]

67. Although Rite Aid Mid-Atlantic implemented a threshold that was common across stores as part of its suspicious order monitoring measures, it differed in important ways from the

---

99 *See* backup materials.

100 McCann Report, ¶ 144.

101 "The report will summarize customers who have purchased quantities of all products containing the identified base code in excess of the threshold for the item. For example all sales and credits of Mckesson items containing Hydrocodone will be added together and reported if the total doses exceeded 8,000 unit." 1_MCKMDL00355041_image.pdf at 355042.

102 Deposition of Nathan J. Hartle, Vice President of Regulatory Affairs and Compliance for McKesson Corporation, July 31-August 1, 2018, Exhibit 17 (stating that "[w]hen a pharmacy customer appears on the report for the first time (because they have met or are about to exceed 8,000 dosage units for the month) the DC will review the orders to determine whether it is justified based on the type of customer, e.g., **national chain account**, and the historical purchases by the customer" and observing that "McKesson currently has a number of contractual commitments with large pharmacy chain customers such as … Rite Aid. None of these customers is a source of the problem identified by DEA involving dispensing of lifestyle drugs without appropriate prescriptions." (emphasis added)).